



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|-------------|----------------------|---------------------|------------------|
| 10/019,570 | 11/08/2001 | Jin Po Lee | 086748-20 | 7953 |
| 30542 | 7590 | 12/16/2003 | | |
| FOLEY & LARDNER | | | EXAMINER | |
| P.O. BOX 80278 | | | ALEXANDER, LYLE | |
| SAN DIEGO, CA 92138-0278 | | | ART UNIT | PAPER NUMBER |
| | | | 1743 | |

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/019,570 | LEE, JIN PO |
| | Examiner Lyle A Alexander | Art Unit 1743 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
 - 4a) Of the above claim(s) 21,23 and 25 is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-20,22 and 24 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1743

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-20,22 and 24, drawn to a device for analysis of multiple analytes in a fluid.

Group II, claim(s) 21,23 and 25 drawn to a device for the separation of a fluid sample.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I requires the special technical feature of a base accommodating a plurality of test strips through slots. Group II is directed to a "V" shaped cup and does not require test strips or the corresponding slots.

During a telephone conversation with Ms. Stacey Taylor on 12/9/03 a provisional election was made with traverse to prosecute the invention of group I, claims 1-20,22 and 24. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21,23 and 25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20,22 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,514,769. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a test device having a base with a plurality of slots that accommodate a plurality of test strips.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These are improper multiple dependent claims because they do not refer back to the claims in the alternative.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-20,22 and 24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Galloway et al. (USP 5,403,551).

Galloway et al. teach an assay device comprising a container (12) having an opening (14) for the addition of the sample to the container. A plurality of test strips (46) is housed within cover (48) where a plurality of ribs (78) fluidically separate the individual strips from one another. The cover containing the strips is mated to cover (30) on the container. A plenum or reservoir (34) is formed within the container and has a plurality of bore (36) that communicate fluid sample to the test strips. Column 4 lines 30+ teach the analytes can be common drugs of abuse such THC, Benzoylecgonine, Morphine, Amphetamine or Phencyclidine.

The claimed base plate has been read on cover (48), the multiplicity of test strips on strips (46), the cover on the cover (30) and the combined sample port and floor on the plenum/reservoir (34)/bore (36) that communicate fluid sample to the test strips. The limitation in claim 1 that each test strip protrudes out of the open end of the slot has been read on the communication of the strips (46) with the bore (36) that contact the

sample (e.g. if the ends of the slots were closed the sample could not contact the strips).

Claims 1-9,18 and 22 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Chipowski (5,976,895).

Chipowski teach a transparent container (11) with an open top (14). A test card (25) comprises a plurality of test strips (26-30) that are spaced apart in parallel on test slide (31) such that the each test strip is fluidically isolated from the others by recessed slots in the card (see col. 4 lines 5+). The results are observed through test windows (50). Column 3 lines 61+ teach the analytes can be common drugs of abuse such THC, Benzoylecgonine(cocaine), Morphine, Amphetamine or PCP

The claimed base plate and cover have been read on test card (25). The multiplicity of test strips on strips (26-30). The limitation in claim 1 that each test strip protrudes out of the open end of the slot has been read on figure 1 which show card (25) protruding from closure (15).

Claims s 1-4,7 and 22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Janin (USP 4,056,359) or Boger et al. (USP 4,518,565).

These references teach a plurality of test strips protruding from a base and cover where the strips are fluidically isolated from each other.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

Art Unit: 1743

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.



Lyle A Alexander
Primary Examiner
Art Unit 1743
